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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/657,685	09/08/2003	Allan H. Conney	RU-0191	1261

7590 10/11/2005

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EXAMINER	
DELACROIX MUIRHEI, CYBILLE	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 10/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/657,685	CONNEY, ALLAN H.	
	Examiner	Art Unit	
	Cybille Delacroix-Muirheid	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 July 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1, 3-5, 7-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-5,7 and 8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

The following is responsive to applicant's amendment received July 8, 2005.

Claims 2, 6 are cancelled. No new claims are added. Claims 1, 3-5, 7-8 are currently pending.

Petition to Correct Inventorship

Applicant's petition to correct inventorship under 37 CFR 1.48(b) and the declaration of Allan H. Conney both received Jul. 8, 2005 have been considered but will not be entered.

Applicant petitions to add Xi Zheng as a co-inventor of the claimed subject matter. However, such a petition must be filed under 37 CFR 1.48**(a)** not under 37 CFR 1.48**(b).** 37 CFR 1.48(b) pertains to amending inventorship due to cancellation or amendment of claims so that fewer than all of the currently named inventors are the actual inventors of the invention being claimed. Please see 37 CFR 1.48(b) and 37 CFR 1.48(a) for guidance on filing a petition to add inventors to a non-provisional application.

Response to Amendment(s)

The previous claim objection set forth in paragraph 1 of the office action mailed March 9, 2005 is withdrawn in view of applicant's amendment and the remarks contained therein.

Applicant's arguments traversing (1) the previous claim rejection under 35 USC 102(a) or (b) over Zheng et al. (paragraph 2 of the office action mailed March 9, 2005); (2) the previous claim rejection under 35 USC 103(a) over Grant et al. and Powell et al. in view of Farmer et al. and Sporn et al. (paragraph 3 of the office action mailed March 9, 2005); and (3) the previous claim rejection under 35 USC 103(a) over Grant et al. and Powell in view of Broder et al. (paragraph 4 of the office action mailed March 9, 2005).

Said rejections are maintained essentially for the reasons given previously in the office action mailed March 9, 2005 with the following additional comment:

Claim Rejection under 35 USC 102(a) or (b) over Zheng et al.

Since applicant's petition is ineffective to amend inventorship in order to prove same inventive entity pursuant to In re Katz, the previous rejection is maintained for reasons already of record. Please see above for comments regarding petitions to change inventorship under 37 CFR 1.48(a).

Claim Rejection under 35 USC 103(a) over Grant, Powell, Farmer and Sporn:

Applicant contends that the examiner has used impermissible hindsight in combining the cited references. The Grant reference does not teach or suggest the use of an agent that induces cell differentiation in the absence of a cyclin-dependent kinase inhibitor nor does Grant teach or suggest the use of PMA in combination with a retinoid. Grant et al. teach that PMA and a retinoid are alternate choices for an agent that induces cell differentiation and there would little desirability for the skilled artisan to use PMA and a retinoid in combination because Grant teaches they are interchangeable. Finally, applicant argues that instant specification teaches that lower therapeutically effective doses of PMA can be administered when administered in combination with a retinoid and the combination produces synergistic results.

Said arguments have been considered but are not found to be persuasive.

The examiner respectfully submits that Grant does suggest the use of a cell differentiation agent in the absence of a cyclin-dependent kinase inhibitor. At pages 2-3, Grant et al. disclose that cell differentiation agents are a class of drugs used for treating cancer, thus suggesting the use of these agents, alone, in the treatment of cancer.

Moreover, applicant's remarks regarding the administration of lower therapeutically effective doses of PMA when administered with a retinoid are not commensurate in scope with the claims.

Additionally, Grant may not suggest the desirability of combining PMA with a retinoid; however, the examiner respectfully submits that the desirability to combine comes from the Farmer and Sporn references. The examiner maintains it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Grant and Powell to treat prostate cancer by administering a composition containing a combination of PMA and the retinoids of Farmer and Sporn because one of ordinary skill in the art would reasonably expect the combined anti-cancer effect of the two compounds to be effective in inhibiting the growth of prostate cancer cells thereby treating the patient suffering from prostate cancer.

Finally, in response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

The rejection is respectfully maintained.

Claim Rejection—35 USC 103 over Grant, Powell and Broder:

Applicant argues that Grant, Powell and Broder do not teach or fairly suggest PMA in combination with paclitaxel. Furthermore, the instant application teaches that paclitaxel, when

used in combination with low therapeutically effective doses of PMA (e.g., 1 ng/ml or 1.6 nM; Table 4 of the specification), can achieve a therapeutic effect at doses of 5 ng/ml which are significantly lower than those disclosed by Broder et al. Therefore, as defined by the teachings of the invention, a therapeutically effective dose of PMA and paclitaxel is lower and non-obvious based upon the synergistic effect afforded by the claimed combination.

Said arguments have been considered but are not found to be persuasive.

Applicant's arguments regarding the administration of low therapeutically effective doses of PMA in combination with paclitaxel are not commensurate in scope with the claims.

Finally, the examiner maintains it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the methods of Grant and Powell to administer a composition containing a combination of 12-O-tetradecanoylphorbol-13-acetate and paclitaxel because one of ordinary skill in the art would reasonably expect the combined apoptosis-inducing activity of 12-O-tetradecanoylphorbol-13-acetate and the cytotoxic activity of paclitaxel to effectively inhibit and thereby treat prostate cancer.

The rejection is respectfully maintained.

Conclusion

Claims 1, 3-5, 7-8 stand rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Cybille Delacroix-Muirheid** whose telephone number is **571-272-0572**. The examiner can normally be reached on Mon-Thurs. from 8:30 to 6:00 as well as every other Friday from 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Christopher Low**, can be reached on **571-272-0951**. The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CDM
Oct. 3, 2005

REBECCA COOK
PRIMARY EXAMINER
GROUP ~~1200~~ 1614